§ 5.605 Dealer and distributor direction to provide data to manufacturers of electronic products.

(a) The Director and Deputy Director for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 537(f) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360nn(f)).

(b) These officials may not further redelegate these authorities.

§ 5.606 Acceptance of assistance from State and Local authorities for enforcement of radiation control legislation and regulations.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to accept assistance from State and Local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 541 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360rr).

(b) These officials may not further redelegate these authorities.

Subpart I—Product Designation; Redelegations of Authority

§ 5.700 Authority relating to determination of product primary jurisdiction.

The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, as product jurisdiction officer is authorized to make a determination under section 563 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–2) respecting the classification of a product as a drug, biological product, device, or a combination product subject to section 503(g) of the act (21 U.S.C. 353(g)), and to assign primary responsibility respecting the organizational component of the Food and Drug Administration that will regulate the product. This official may not further redelegate this authority.

§ 5.701 Premarket approval of a product that is or contains a biologic, a device, or a drug.

(a) For a product that is or contains a biologic, a device, or a drug, the following officials in the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, or Center for Drug Evaluation and Research who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) and the Directors of the Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(2) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director, Office of Device Evaluation, CDRH.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) These officials may not further redelegate this authority.

Subpart J—Imports and Exports; Redelegations of Authority

§ 5.800 Imports and exports.

(a) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized, under section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of food, drugs (including biological products), devices,

or cosmetics imported or offered for import.

(2) Determine whether such articles are in compliance with the act.

(3) Authorize relabeling or other compliance actions to bring articles into compliance under the Act.

(4) Supervise such compliance actions.

(b) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH); the Director and Deputy Director, Office of Compliance, CDRH; Regional Food and Drug Directors; District Directors; and the Director, St. Louis Branch, are authorized, under section 536 of the act (21 U.S.C. 360mm), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of electronic products imported or offered for import to determine whether such products are in compliance with section 534 of the act (21 U.S.C. 360kk).

(2) Refuse admission of noncomplying products and notify the Secretary of the Treasury of such refusal.

(3) Supervise operations to bring noncomplying products into compliance under section 534 of the act (21 U.S.C. 360kk).

(4) Refuse or grant permission and time extensions to bring noncomplying products into compliance with section 534 of the act (21 U.S.C. 360kk) in accordance with a corrective action plan approved by the Directors, Offices of Compliance Surveillance and Biometrics, CDRH.

(c) The following officials are authorized, under section 538(b) of the act (21 U.S.C. 360oo(b)), to exempt persons from issuing a certification, as required by section 534(h) of the act (21 U.S.C. 360kk(h)) for electronic products imported into the United States for testing, evaluation, demonstrations, or training, which will not be introduced into commerce and upon completion of their function will be destroyed or exported in accord with U.S. Customs Service's regulations:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) Regional Food and Drug Directors.

(4) District Directors.

(5) The Director, St. Louis Branch.

(d) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to exercise all of the functions of the Commissioner of Food and Drugs (Commissioner) under section 362 of the Public Health Service Act (42 U.S.C. 265) that relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products, and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

(e) The following officials are authorized to perform all the functions of the Commissioner pertaining to exportation of medical devices under section 801(e) of the act (21 U.S.C. 381(e)):

(1) For medical devices assigned to their respective organization:

(i) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director and Deputy Director, Division of Program Operations, Office of Compliance, CDRH.

(iv) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(v) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(f) The following officials are authorized to perform the functions of the Commissioner for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the act (21 U.S.C. 381(d)(2)) for emergency medical care:

(1) The Director and Deputy Directors, Center for Biologics Evaluation

and Research (CBER) and the Director, Office of Compliance and Biologics Quality, CBER.

(2) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) and the Director and Deputy Director, Office of Compliance, CDER.

(g) These officials may not further redelegate these authorities.

§ 5.801 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382(b)(2) and (b)(3)), to grant or deny petitions to export unapproved new drugs and biological products and to issue notices of receipt of such petitions for human drugs assigned to their respective organizations:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(4) The Director and Deputy Director, Office of Compliance, CDER.

(b) The following officials are authorized, under section 802(e) of the act (21 U.S.C. 382(e)), to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease or another disease as described in section 802(e) for human drugs assigned to their respective organizations:

(1) The Director and Deputy Directors, CBER.

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(4) The Director and Deputy Director, Office of Compliance, CDER.

(c) The following officials are authorized, under section 351(h) of the Public Health Service Act (42 U.S.C. 262(h)), to approve or disapprove an application to export a partially processed biological product:

(1) The Director and Deputy Directors, CBER.

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(d) These officials may not further redelegate these authorities.

§ 5.802 Manufacturer's resident import agents.

The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to reject manufacturer's designation of import agents under § 1005.25(b) of this chapter. These officials may not further redelegate this authority.

Subpart K—Orphan Products; Redelegations of Authority

§ 5.900 Orphan products.

(a) The Director, Office of Orphan Products Development (OPD), Office of the Senior Associate Commissioner (OSAC), Office of the Commissioner (OC), is authorized to issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for biologics licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, OPD, OSAC, OC, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and